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K032986
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IV. 510(k) SUMMARY

Submitted by:

Scion Cardio-Vascular, Inc.
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Contact Person: Ramon Augusto Paz

Date Prepared: February 18, 2004

Proprietary Name: Scion Cardio-Vascular ***Clo-Sur*^{PLUS} P.A.D.**™

Common Name: Topical Hemostasis Pad

Classification: Unclassified

Classification Name: Topical Wound Dressing Pad

Predicate Device:

- Advanced Medical Solutions, LTD. - K024298 – **Antimicrobial Dressing**
- Perclose, Inc. – K021062 – **ChitoSeal**
- T-Scientific, Inc. – K030334 – **T-PAD**
- Marine Polymer Technologies - K984177 – **SyvekPatch**

Device Description:

The Scion Cardio-Vascular ***Clo-Sur*^{PLUS} P.A.D.** is a soft, non-woven pad that provides an optimal wound-healing environment, combining an effective antibacterial barrier activity with exudates management.

***Clo-Sur*^{PLUS} P.A.D.** has demonstrated in-vitro antibacterial activity meant to prevent microbial colonization and penetration of the dressing.

An in-vitro study was performed to demonstrate the effectiveness of the Clo-Sur P.A.D., to act as an antimicrobial substance against bacteria and fungi. The test protocol as designed assessed by quantitative assay the antimicrobial properties of the Clo-Sur P.A.D. over a defined 24-hour time frame.

To determine the effectiveness of the Clo-Sur P.A.D., three product concentrations were prepared and challenged with a 10^5 CFU/mL concentration of each of the following organisms: *Escherichia coli* (ATCC 8739),

Pseudomonas aeuroginosa (ATCC 9027), *Staphylococcus aureus* (ATCC 6538), *Bacillus subtilis* (ATCC 6633), *Enterococcus faecium* (ATCC 15335), *Streptococcus pyogenes* (ATCC 12347), *Candida albicans* (ATCC 10231) and *Aspergillus niger* (ATCC 16404). The test solutions were then samples at time points of 0, 4 and 24 hours to determine the organism concentration. A positive control was run in parallel with each of the organism to determine the organism growth profile without the presence of the test article.

The study demonstrated that at the highest concentration of 0.15 grams, the Clo-Sur P.A.D. reduced the concentration of both bacteria and fungi over the 24-hour course of the study.

The clinical significance of the findings in this vitro study is unknown.

***Clo-Sur*^{PLUS} P.A.D.** is a sterile topical hemostasis pad, packed in a foil pouch and sterilized by E-beam radiation to a 10^{-6} SAL.

Intended Use:

The Scion Cardio-Vascular ***Clo-Sur*^{PLUS} P.A.D.**, is intended for the local management of bleeding wounds and to provide a barrier to bacterial penetration of the dressing in all patients and for the promotion of rapid control (hemostasis) of bleeding in patients following hemodialysis and for those on anticoagulation therapy. The dressing is indicated for the following wounds: lacerations, abrasions, nose bleeds, and the skin surface puncture sites for vascular procedures, percutaneous catheters or tubes.

Technological Characteristics:

The Scion Cardio-Vascular ***Clo-Sur*^{PLUS} P.A.D.**, a soft, non-woven pad made of a proprietary formulation of poly-D-glucosamine and poly-N- acetylglucosamine derived from chitosan. The natural biological property of this material gives the ***Clo-Sur*^{PLUS} P.A.D.** an advantage as an effective bacterial barrier while providing for an optimal wound-healing environment.

Several biomedical applications of poly-D-glucosamine and poly-*N*-acetylglucosamine have been reported. The studies represent research on the safety and use of these materials, which has been published over a period of decades by scientists from around the world. This large body of scientific literature satisfies the requirement that a general recognition of safety requires common knowledge about the substance throughout the scientific community. This formulation has many useful and advantageous properties in their application as a wound

dressing, namely biocompatibility, biodegradability, hemostatic activity, anti-infectional activity.

The technological characteristics of the ***Clo-Sur***^{PLUS} **P.A.D.** are the same as the predicate devices. The Scion Cardio-Vascular ***Clo-Sur***^{PLUS} **P.A.D.** works in the same manner as the approved predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 1 2004

Mr. Ramon Augusto Paz
Director of Quality Assurance & Regulatory Affairs
Scion Cardio-Vascular, Inc.
14256 SW 119 Avenue
Miami, Florida 33186

Re: K032986
Trade/Device Name: Clo-Sur ^{Plus} P.A.D.
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 17, 2003
Received: December 19, 2003

Dear Mr. Paz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

VI. Indications for Use

510(k) Number (if known): **K032986**

Device Name: ***Clo-Sur*^{PLUS} P.A.D.**

Indications For Use:

The Scion Cardio-Vascular ***Clo-Sur*^{PLUS} P.A.D.**, is intended for the local management of bleeding wounds and to provide a barrier to bacterial penetration of the dressing in all patients and for the promotion of rapid control (hemostasis) of bleeding in patients following hemodialysis and for those on anticoagulation therapy. The dressing is indicated for the following wounds: lacerations, abrasions, nose bleeds, and the skin surface puncture sites for vascular procedures, percutaneous catheters or tubes.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K032986